

**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

**REMARKS**

Claims 5-12 have been amended and claims 13-25 have been cancelled. Claims 5-12 and 26 are now pending. It is believed that no new matter has been added. The applicants reserve the right to pursue the subject matter of claims 13-25 in a divisional application.

***Information Disclosure Statement***

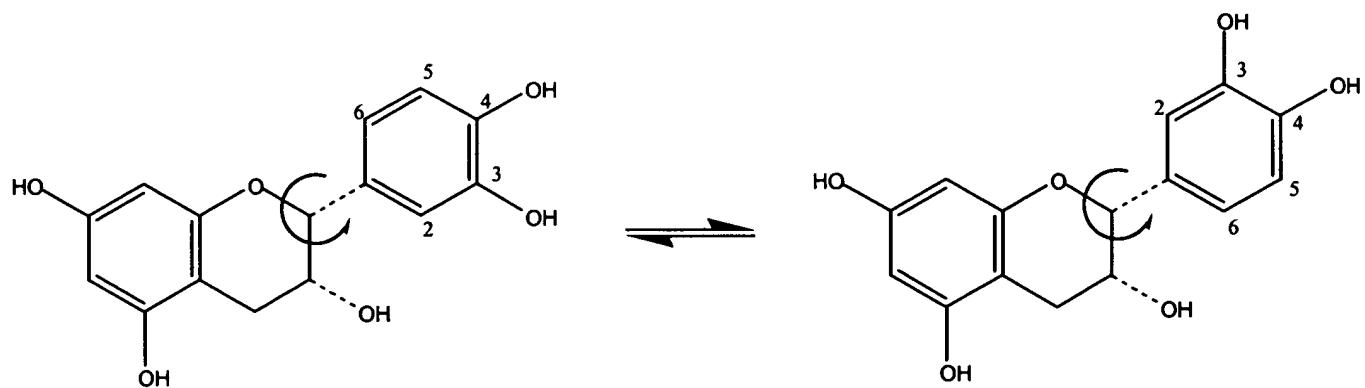
While an additional copy of the references cited in the IDS are being provided, the examiner is directed toward the applicants transmittal letter for filing under 35 U.S.C. 371 which indicates that a copy of the references were submitted and the PTO acknowledged that such references were received (see Form PCT/DO/EO/903 - signed by Vonda Wallace). As such, the date of the originally filed IDS is still valid and the applicants' request consideration of the references in the next office action.

For situations where it appears the references become separated from the file after receipt by the PTO (especially when the references are U.S. or foreign patents), the applicants request that the examiner, in the interest of advancing prosecution, utilize their databases (e.g. EAST/WEST, FPAS or WPIDS) to obtain the references of record or at the very least contact the applicants so that an additional copy can be faxed for their consideration. If the examiner contacted the

applicants about the missing references, there is no Interview Summary Record of such a discussion.

### ***Specification Objections***

The specification was objected to because of the structure listed for the epicatechin was stated by the examiner to be different than the structure listed in the CAS Registry files. However, the structures are the same compounds, i.e. the 3,4-dihydroxyphenyl component of the epicatechin can rotate around the 2R bond, see below:



With regard to Example 2 on page 17, it is unclear what is the basis for the examiner's objection. It is clear that green tea extract is intended to be part of the skin cream of example 2 which is consistent with the applicants' disclosed invention (i.e. adequately described). If the examples are objected to because no specific amount of green tea extract is disclosed in the list of ingredients, the examiner is reminded that no recitation of working examples are necessary (i.e. adequately enabled), especially in the present application where other working examples are present (see MPEP 2164.02).

### **35 U.S.C. 112, first paragraph rejection**

Claims 5-12 have been amended to remove the term "prophylaxis" and as such this portion of the rejection is believed to have been addressed.

Claim 26 was rejected by the examiner as not being adequately described for "strengthening the lipid barrier or increasing the synthesis rate of ceramides of human skin". However, no reasons or explanation was given by the examiner as to why it is believed that the applicants have not adequately described their invention.

The examiner is reminded that MPEP 2163, section I. A. states:

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the **PTO has the initial burden of presenting evidence or reasons** why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). - emphasis added by applicants.

### **35 U.S.C. 112, second paragraph rejection**

Claims 5-12 were rejected as being indefinite for using the phrase dry skin "conditions". While the applicants assert that the phrase has clear meaning to one of ordinary skill in the cosmetics art, the term "conditions" has been deleted. The applicants reserve the right to pursue the claims prior to amendment in a divisional applications if necessary.

Claims 5-12 were rejected as being indefinite for using the term "a therapeutically effect (sic) amount". This is a commonly used phrase which can be found in any number of previously

issued patents with method of use claims (see Class 424 and Class 514 especially) and is intended to refer to the effective amount for the disease/condition which is being treated as stated in the preamble of the claim. The applicants submit that the claim language is definite as written, but if this is the only issue preventing a Notice of Allowance, the examiner is authorized to incorporate redundancy by drafting an Examiner's Amendment which substitutes the phrase "a therapeutically effective amount" for the phrase "a therapeutically effective amount for the treatment and/or care of dry skin".

See above explanation ("Specification Objections") about the figure on the bottom of page 4 in the specification which supports the assertion by the applicants that Claim 8 is definite as written.

### ***35 U.S.C. 102(b) rejection***

Claims 5-12 and 26 remain rejected (after the applicants' amendment) by the examiner as being anticipated by the abstract for BR 9303217 A (Kurose et al.)

Kurose et al. does not anticipate the applicants' claims 5-12 as amended. MPEP 2131 states that "A claim is anticipated only if each and every element *as set forth in the claim is found*, either expressly or inherently described, in a single prior art reference.....The identical invention *must be shown in as complete detail as is contained in the ...claim.*" (emphasis added by applicants). As such, Kurose et al. does not teach the weight limitations of the catechin components or direct the skilled artisan to a specific method of use, i.e. Kurose et al. only hypothesizes ("may have") about a laundry list of potential utilities (ten in all).

Kurose et al. does not disclose the invention represented by the applicants claim 26 (i.e. a method of strengthening the lipid barrier and/or increasing the synthesis rate of ceramide of human skin)

and as such does not anticipate this claim.

Claims 5-12 and 26 remain rejected (after the applicants' amendment) by the examiner as being anticipated by Znaiden et al. (U.S. Patent 5,523,090).

It was presumed that claims 5-12 were included in the rejection because of the use of the term "conditions"??? In any event, the claims as amended clearly define the method of use to be for the dry skin which is not equivalent to the treatment of cellulite. Likewise, Znaiden et al. does not teach the inventive concept represented by the applicants' claim 26.

Claim 26 remains rejected (after the applicants' amendment) by the examiner as being anticipated by Ahluwhalia (WO 96/26705).

Ahluwhalia method of use is directed toward reduction of mammalian hair growth which does not anticipate a method of strengthening the lipid barrier and/or increasing the synthesis rate of ceramide of human skin as stated in the applicants' claim 26.

### **35 U.S.C. 103(a) rejection**

Claims 5-12 and 26 remain rejected (after the applicants' amendment) by the examiner as being obvious over Kurose et al. (abstract) in combination with Znaiden et al. (each reference cited above).

As stated above, Kurose et al. does not teach the applicants invention as Kurose et al. does not describe the applicants weight limitations for catechins and does not teach the specific method of use claimed by the applicants.

Znaiden et al. does not remedy the deficiencies of the Kurose et al. references as it does not recognize using the catechins for the method described by the applicants and are directed toward compositions which have different components and different intended use. Furthermore, there is no explanation as to the motivation for combining the teachings of Znaiden et al. into the teachings of Kurose et al., i.e. statement of "reasonable expectation of success" by the examiner only establishes that the references *could be* combined (see MPEP 2143.02). However, this does not supply the motivation or suggestion to modify the reference cited as described in MPEP 2143.01; i.e. the combination represents hindsight or an obvious-to-try rationale.

***Closing***

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

Applicants believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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**CERTIFICATE OF MAILING**

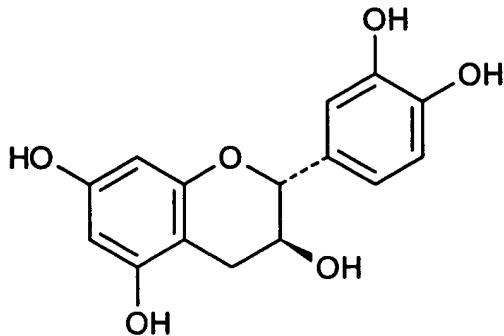
I hereby certify that the foregoing Amendment under 37 CFR § 1.111 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, Washington, D.C. 20231, on the date indicated below:

Date: **8 March 2002**

By Howard C. Lee  
Howard C. Lee

**COPY OF CLAIMS SHOWING AMENDMENTS MADE**

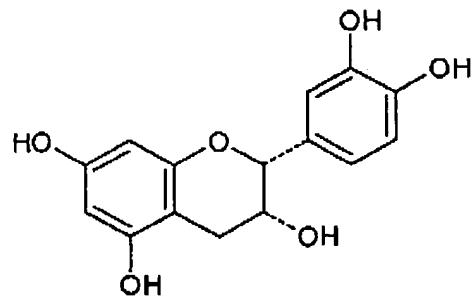
5. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] in a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of a composition comprising of 0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof, based on the total weight of the composition.
6. The method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin or gallic ester of a catechin are selected from the group consisting of (-)-catechin, (+)-catechin, (-)-catechin gallate, (-)-gallocatechin gallate, (+)-epicatechin, (-)-epicatechin, (-)-epicatechin gallate, (-)-epigallocatechin, and (-)-epigallocatechin gallate.
7. The method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin is



or a gallic ester thereof. --

8. The method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin is

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or a gallic ester thereof.

9. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin or gallic ester of a catechin is obtained from a plant.
10. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 9, wherein the catechin or gallic ester of a catechin is obtained from a plant from the *Theaceae* plant family.
11. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 9, wherein the catechin or gallic ester of a catechin is obtained from the plant species *Camellia sinensis*.
12. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] in a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of an extract from a plant or plant parts which comprises a catechin, a gallic ester of a catechin, or mixtures thereof.

26. A method for strengthening the lipid barrier and/or increasing the synthesis rate of ceramide of human skin in a human in need thereof that comprises applying to the skin of a patient in need thereof a therapeutically effect amount of the composition according to Claim 13.